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Attorneys for Defendant RAMESH BALWANI

DAVIS WRIGHT TREMAINE LLP

IN THE UNITED STATES DISTRICT COURT

THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

ELIZABETH A. HOLMES and
RAMESH "SUNNY" BALWANI,

Defendants.

Case No. cr-18-00258-EJD

MR. BALWANI'S REPLY IN SUPPORT OF DEFENDANTS' MOTION TO COMPEL DISCOVERY AND BRADY MATERIALS

Date: June 28, 2019
Time: 10 a.m.
CTRM: 4

Hon. Edward J. Davila

I. INTRODUCTION

Mr. Balwani files this reply specifically to address the government's suggestion that an Order granting this Motion is unnecessary, on the theory that the Court should rely on the FDA and CMS to make satisfactory document productions only in response to subpoenas Mr. Balwani served in the parallel SEC civil case. In fact, the agencies' responses to Mr. Balwani's civil subpoenas show that the requested Order is essential to ensure timely production and efficient progress in this criminal case.

Mr. Balwani has a unique perspective on this issue. Although Mr. Balwani served CMS and FDA with civil subpoenas in September 2018, neither agency has yet to begin meaningful compliance with the requests. Now, hoping to avoid a Court order directing the government to provide defendants with documents crucial for this case, particularly internal communications, the government submits letters from the agencies describing their intent to *begin* producing unspecified documents weeks from now—more than *nine months* after service of the subpoenas in the civil case. The agencies' letters should provide the Court with cold comfort. They promise only a process that would allow the agencies to choose or even cherry-pick what to collect and produce while continuing to object to civil discovery, laying the foundation for still more motion practice.

The Court should not rely on assurances that the agencies will now do what they should have done many months ago. Instead, the Court should issue an order in this case requiring the government to produce all material in the possession of CMS and FDA responsive to defendants' requests, including all internal correspondence from all custodians involved in the agencies' interactions with Theranos. An order from this Court pursuant to Rule 16 and *Brady* is required to honor Mr. Balwani's Constitutional rights to a fair trial and to present a complete defense in this criminal case where he faces serious charges with the full might and resources of the United States government arrayed against him. *Crane v. Kentucky*, 476 U.S. 683, 690 (1986). The internal communications within CMS and FDA about Theranos and its business and laboratory operations could not be more central to this case. Indeed, if the DOJ is actually trying to get the agencies to produce all of the required documents, it should welcome an order from this Court

requiring production. The agencies' foot-dragging over the last nine months, discussed below, demonstrate that only an Order from this Court in this case will lead to full production.

II. ARGUMENT

A. The Agencies Have Failed to Timely Comply with Mr. Balwani's Subpoenas.

On September 12, 2018, Mr. Balwani issued subpoenas in the SEC matter to the FDA and CMS. Since then, Mr. Balwani has made various accommodations to reduce the burden on the agencies and expedite production. In particular, Mr. Balwani (1) initially offered to narrow the CMS subpoena to the period 2013 to 2016, *see* Cazares Decl. Ex. A at 2-3; (2) tried to identify relevant custodians, even with limited information, to focus searches for internal communications, *id*. at 3; (3) negotiated a protective order to cover the agencies' future productions, SEC Dkt. 83; and (4) obtained a waiver from the Theranos assignee as to production of documents containing trade secrets and confidential commercial information, Opp'n Ex. F.

Despite these accommodations, the FDA and CMS have produced a mere 161 documents in response to Mr. Balwani's subpoenas—a sparse production, given their years of regulatory interaction with Theranos, that did not include internal communications. Cazares Decl. ¶ 3. Both agencies have put forward a plethora of objections to avoid producing all of their internal communications relating to Theranos. Claims from the agencies that they produced other documents that the prosecution wanted are obviously insufficient.

After thus being rebuffed for over seven months, Mr. Balwani, on April 2, 2019, served counsel for the FDA and CMS with draft letter motions to compel production of documents pursuant to the subpoenas. Cazares Decl. Ex. B at 3. The prospect of motions briefly brought the agencies to the table. On April 17, 2019, the agencies' counsel agreed to a further meet and confer with Mr. Balwani regarding the proposed motions to compel. Cazares Decl. Ex. B at 1. Two days later, however, the government filed its motion to stay discovery in the SEC case. SEC Dkt. No. 67. Although the Court clearly stated at the April 22, 2019, status conference that

SEC discovery would continue pending disposition of the stay motion, counsel for the agencies rebuffed efforts to discuss the subpoenas until the Court decided the motion. *Id*. Ex. C.[1]

Promptly after the Court denied the Motion to Stay the SEC case, Mr. Balwani again requested a meet and confer. *Id*. Ex. D. On June 21, 2019, new counsel for the FDA and CMS responded with an email that, among other things, reported that "CMS and FDA currently anticipate that they will *begin* additional productions . . . in *approximately* a month." *Id*. Ex. E at 1 (emphasis added). But the email called that "estimate" a mere "goal," suggesting the agencies might not even start producing documents in July if they have "technical or other difficulties" or if "necessary resources" are not "available." *Id*. Moreover, the California Department of Public Health ("CDPH") announced with the filing of the government's opposition brief that they lost crucial documents from their December 2013 inspection of Theranos's clinical laboratory, *see* Opp'n Ex. E, an inspection carried out by CDPH as the agent of CMS. *See* 45 C.F.R. § 2.2. The lost documents are officially federal records, *see* Cazares Decl. ¶ 11, showing that CMS even failed to properly honor the litigation hold that DOJ directed them to put in place.[2]

Thus, over nine months after serving subpoenas for documents vital to his defense, Mr. Balwani has neither the documents nor a firm commitment for their production—and finds that some agency documents have even been lost.

[1] Even with the Motion to Stay pending, Mr. Balwani obtained the agencies' agreement to a Supplemental Protective Order for FDA and CMS Information, SEC Dkt. 83, and secured the Theranos assignee's waiver of trade secrets and other protections, which the FDA and CMS demanded, Opp'n Ex. F.

[2] Under federal law, employees of state regulatory agencies engaged in "performing survey, certification, or enforcement functions" are deemed "employees" of HHS, just like CMS employees. 45 C.F.R. § 2.2. Now, faced with this motion, CMS represents that documents related to the 2013 CLIA survey by CDPH "are no longer available," even though the government issued a litigation hold to the HHS Office of General Counsel regarding *all* communications by CMS employees, Mot. Ex. 8, which includes the CDPH surveyor who performed the 2013 Theranos CLIA survey. Thus, materials relevant to this action now appear to be "unavailable" due to CMS inaction and its failure to previously secure CMS records of surveys conducted on its behalf.

B. The Agencies' Letters Do Not Provide Sufficient Assurances to Avoid an Order.

The agencies' failure to comply in any meaningful way with the September 2018 subpoenas in the SEC case provides the lens through which the Court should view the government's argument that the Court should now trust the FDA and CMS to produce documents they should have produced months ago. *See* Opp'n 5-6. The FDA and CMS letters filed with the Court (Opp'n Exs. C, D) amount to nothing more than pledges to review documents, reassert objections, and use discretion in deciding what to produce. They thus promise nothing more than a continuation of the same conduct.

FDA. The FDA's letter of June 7, 2019 (Opp'n Ex. C) commits to nothing. It amounts to a list of excuses to avoid production, and promises only continued disputes.

The FDA begins with the erroneous assertion that most of the requested materials are irrelevant to this case. Opp'n Ex. C at 2. It then argues "burden," saying that it identified 62,000 documents based on key word searches of forty-five custodians' files, which now must be subjected to a laborious "line-by-line" review for "privilege and other protections." *Id*. The FDA says it intends to use this process to redact: (1) trade secret information; (2) confidential commercial information; (3) attorney-client communications; (4) attorney work product; (5) personal privacy information; (6) privileged investigatory files; and (7) deliberative process and/or other protected information. *Id*. at 3.

The FDA's invocation of the deliberative process privilege reneges on its prior agreement, in the discussions with Mr. Balwani regarding the subpoena in the SEC case, to waive deliberative process privilege claims and produce internal FDA communications. Cazares Decl. Ex. F at 3. Indeed, the FDA produced several internal communications during the government investigations, *id.* ¶ 10, but now states for the first time, in its June 7, 2019 letter, that it will withhold materials under a claim of deliberative process privilege. Opp'n Ex. C.

Further, the FDA says it must take the time to manually de-duplicate previously produced documents (Opp'n Ex. C at 2), an unnecessary process that appears calculated to further delay production. The FDA concedes the Theranos assignee's waiver of trade secret and commercial information protections eliminates its obligation to redact some material, but asserts it will not

re-produce responsive materials that it previously produced with heavy redactions in response to FOIA requests. *Id*. at 3. In short, the FDA's letter gives the Court no assurance as to how much (*if any*) substantive information the FDA will produce, and when the production will occur.

The requested Order would overcome most of the hurdles the FDA has erected to delay production. As the FDA admits, the "need to redact privileged and otherwise confidential information from the newly-collected documents" vanishes with entry of an appropriate Order. *Id*. at 3 (FDA "cannot lawfully produce any responsive documents that would reveal such information *absent a court order*") (emphasis added); *see United States v. W.R. Grace*, 455 F. Supp. 2d 1140, 1148 (D. Mont. 2006) (granting discovery order and rejecting government trade secret, privacy, and deliberative process privileges claims for withholding agency documents); *Agility Pub. Warehousing Co. v. Dep't of Def.*, 110 F. Supp. 3d 215, 228-29 (D.D.C. 2015) (holding that order granting motion to compel subpoena compliance constitutes "other appropriate legal authorization" permitting disclosure of trade secrets under 18 U.S.C. § 1905).

Mr. Balwani asks the Court to enter an Order in this case to resolve the FDA's concerns and expedite production. Otherwise, the parties will be before the Court months from now to address the same issues that have impeded Mr. Balwani's efforts to obtain FDA records since September 2018 in the SEC case.

CMS. Like the FDA, CMS seeks to avoid an Order by suggesting it will do better than it has over the last nine months. Opp'n Ex. D. But the CMS letter likewise rings hollow.

CMS has produced a grand total of 43 documents in response to the September 2018 subpoena. Cazares Decl. ¶ 3. As noted above, claims from CMS that it produced other documents that DOJ or SEC wanted for their joint investigation are not sufficient. During the lengthy meet and confer process dating from the fall of 2018, CMS steadfastly refused to produce *any* internal communications relating to Theranos. Cazares Decl. Ex. G at 2. CMS now says it will produce internal communications relating to Theranos, but it is not clear whether CMS is now agreeing do more than search for communications for the few custodians it calls the "CLIA group." Opp'n Ex. D. CMS's past conduct, combined with its silence on which

document custodians it will search, indicates that it may be planning to unilaterally limit the search, cherry-pick custodians and their documents, and then claim full compliance.

Absent an order from this Court, CMS will likely revert to the same objections and delays that have stalled Mr. Balwani's efforts to obtain its records. The Court should enter an Order requiring CMS to produce without limitations.

III. CONCLUSION

For the foregoing reasons, the Court should reject the government's proposed alternatives to meet its discovery obligations in this criminal case and grant the requested order compelling disclosure by the government of the requested materials in this case.

DATED: June 24, 2019

Respectfully submitted,

DAVIS WRIGHT TREMAINE LLP

Jeffrey B. Coopersmith
Stephen A. Cazares

CORR CRONIN LLP

By: */s/ Steven W. Fogg*
Steven W. Fogg
Joshua T. Ferrentino

Attorneys for Defendant
RAMESH BALWANI

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Attorneys for Defendant RAMESH BALWANI

DAVIS WRIGHT TREMAINE LLP

IN THE UNITED STATES DISTRICT COURT

THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

ELIZABETH A. HOLMES and
RAMESH "SUNNY" BALWANI,

Defendants.

Case No. cr-18-00258-EJD

DECLARATION OF STEPHEN A. CAZARES IN SUPPORT OF MR. BALWANI'S REPLY IN SUPPORT OF DEFENDANTS' MOTION TO COMPEL DISCOVERY AND BRADY MATERIALS

Date: June 28, 2019
Time: 10 a.m.
CTRM: 4

Hon. Edward J. Davila

I, Stephen A. Cazares, declare as follows:

1. I am a partner with the law firm of Davis Wright Tremaine LLP and am an attorney defending Ramesh Balwani in this matter and in the SEC matter. I make this declaration in support of Mr. Balwani's Reply in Support of Defendants' Motion to Compel Discovery and Brady Materials.

2. Attached as Exhibit A is a true and correct copy of a letter from Jeffrey Coopersmith, my partner at Davis Wright Tremaine, to Rebecca Falk, an Assistant United States Attorney representing both the FDA and CMS, dated February 14, 2019.

3. In response to the subpoenas served by Mr. Balwani on FDA and CMS, the agencies have directly produced to Mr. Balwani a total of 161 documents. CMS produced 43 of these documents, and FDA produced 118 documents.

4. Attached as Exhibit B is a true and correct copy of an email conversation between Ms. Falk and Mr. Coopersmith, dated between April 2 and April 17, 2019.

5. Attached as Exhibit C is a true and correct copy of an email conversation between Ms. Falk and myself, dated between May 31 and June 3, 2019.

6. Attached as Exhibit D is a true and correct copy of an email conversation between Ms. Falk and myself, dated between June 14 and 17, 2019.

7. Attached as Exhibit E is a true and correct copy of an email conversation between Claire Cormier, an Assistant United States Attorney representing both the FDA and CMS, Mr. Coopersmith, and myself, dated between June 14 and 21, 2019.

8. Attached as Exhibit F is a true and correct copy of a letter from Laura Draski, representing the FDA, to Mr. Coopersmith, dated March 22, 2019.

9. The FDA produced documents to the SEC and/or DOJ during their investigations into this matter, which were subsequently produced to Mr. Balwani. Those productions include some internal FDA communications.

10. Attached as Exhibit G is a true and correct copy of a letter from Lindsey Turner, representing CMS, to Mr. Coopersmith, dated September 27, 2018.

11. On a June 29, 2019 telephone conference, counsel for the California Department of Public Health ("CDPH") confirmed to me that CDPH's 2013 CLIA survey of Theranos was a CMS survey and all records related to the 2013 CLIA survey are CMS records.

Executed this 24th day of June, 2019 at Los Angeles, California.

/s/ Stephen A. Cazares
Stephen A. Cazares

EXHIBIT A

Davis Wright Tremaine LLP

Suite 3300
920 Fifth Avenue
Seattle, WA 98104-1610

Jeffrey B. Coopersmith
(206) 757-8020 tel
(206) 757-7020 fax

jeffcoopersmith@dwt.com

February 14, 2019

VIA EMAIL – rebecca.falk@usdoj.gov

Rebecca A. Falk
Assistant United States Attorney
United States Attorney's Office
Northern District of California
450 Golden Gate Avenue, 9th Floor
San Francisco, California, 94102

Re: *SEC v. Balwani*; Case No. 5:18-cv-01603-EJD
Balwani Subpoena to CMS

Dear Ms. Falk,

This letter sets forth our response on behalf of Mr. Balwani to the February 11, 2019 email to my colleagues from Lindsay Turner, an attorney with the Office of the General Counsel at the U.S. Department of Human Services (HHS). This letter also addresses and responds to the issues discussed during the February 12, 2019, meet and confer conference call attended by you, Ms. Turner, and my colleagues, Ben Byer and Amanda McDowell. As you know, our subpoena to CMS, an agency of the United States Government that is part of HHS and represented by the Department of Justice, was served many months ago in September 2018. In all of this time, we received only one very small production from CMS, on January 3, 2019, consisting of 43 documents. The January 2019 production was incomplete and a large volume of responsive documents has not even been searched for yet, let alone produced. During the government's investigation and based on requests from the investigating agencies, CMS collected and supplied about 250,000 pages of documents.

We can no longer tolerate the delay in producing the materials that we have requested as part of Mr. Balwani's defense. As outlined below, please let us know no later than February 20th: (1) whether the government will commit to a date certain for production of the subpoenaed documents, including the internal CMS communications requested by Mr. Balwani below, and (2) whether the government will commit to a date certain for production of a privilege log for any CMS documents it withholds under a claim of privilege, as required by Ninth Circuit authority. Without a firm commitment on these issues, or if the date certain is unreasonable given the passage of time and needs of the case, we will have to seek appropriate relief from the Court.

We appreciate that the government is finally working to respond meaningfully to Mr. Balwani's subpoena, but this work has only come after a significant delay of over five months that has already prejudiced Mr. Balwani's ability to prepare his defense and identify CMS witnesses that he may need to depose in this case. To be clear, the CMS documents that were produced to Mr. Balwani by the SEC and DOJ were documents that were collected for the government's investigation into Theranos before this case was initiated. We did not ask you to reproduce those documents, and the government and its agency did not have to do any work gathering or producing these documents in response to Mr. Balwani's subpoena.

We learned for the first time this week that the government now plans to construct a database to load and review additional responsive CMS documents. We understand from the February 12 meet and confer call that the government anticipates that this database could take several weeks to construct, after which time additional documents will have to be loaded, CMS personnel will have to be given access to the database, and only then can the government begin reviewing additional documents that may be produced. You informed my colleagues on the February 12 call that the government can give us no time frame or date certain for when this process will be completed. Especially in view of the lengthy delay since we served the subpoena, we cannot be confident that weeks will not turn into many months.

We are also troubled by the fact that this endeavor is just now being planned. Through our lengthy meet and confer process, we have tried to ease any burden facing the government, expedite this process, and avoid unnecessary Court involvement. Indeed, Mr. Balwani has made substantial concessions during this process, such as conducting research and providing CMS with names of third parties and CMS custodians, working to narrow time frames, and responding at length to each of CMS's requests for our legal position on various issues. We will also forego for the time being our demand for production of documents relating to Medicare reimbursement of Theranos blood testing, although we reserve the right to renew our request for these materials should the need arise based on further developments in discovery.

The below sets forth our requests, pared down to the maximum extent possible in view of the issues in the case. If the government is unable to agree to these requests, we are prepared to bring these issues before the Court seeking an order directing the government to comply with its obligations under Rule 45 in a timely manner.

Internal CMS Communications (Requests 1, 3- 8, 16)

The government has agreed to search for internal CMS communications from November 20, 2015 – December 31, 2016. As we have discussed, this time frame omits key events relating to CMS that are relevant to Mr. Balwani's defense. For instance, CMS or its agent inspected Theranos in December 2013, made an inspection request in June 2015, conducted another

inspection in September 2015, obviously discussed internally the findings of that inspection, and came back for a third inspection in November 2015. We are willing at this time to forego collection and production of documents created after July 7, 2016, so you may omit the period after that date from your collection efforts. We reserve the right to renew our request for these materials should the need arise based on further developments in discovery.

The government must therefore search for and produce internal communications between **September 1, 2013 to July 7, 2016**, in order to capture the entire period when communications leading up to, during, and in the aftermath of the audits and inspections are likely to have occurred. We have explained the relevance of these communications in extensive detail in prior communications, including Ms. McDowell's February 5th email, but the bottom line is that CMS was the primary regulator and inspection authority for Theranos's labs, and the complaint is filled with allegations that Mr. Balwani misrepresented the nature and capabilities of the laboratory-developed tests that CMS was regulating and inspecting.

Regarding custodians, it is the government's responsibility to identify custodians who were involved with the regulatory and inspection issues for Theranos to capture all responsive documents. Please let us know the custodians from which you will be collecting documents, but those custodians should include all custodians that may have responsive documents and at least the following individuals who it appears were reviewing Theranos's labs based on the documentary evidence we have seen so far: Sarah Bennett, Karen Dyer, Karen Fuller, Penny Keller, Gary Yamamoto, Patrick Conway, Mandy Cohen, Megan O'Reilly, Debbra Hattery, Danielle Andres, Thomas Hamilton, Jan Tarantino, Judy Yost, Lisa Watkins, Maria Martino, Kate Goodrich, Jean Moody-Williams, Shari Ling, and Renee Henry.

Privilege Log

The government has informed us that it has "no position" on whether it plans to produce a privilege log for any internal communications it will withhold on the grounds that the material is covered by the deliberative process privilege. Any assertion of the deliberative process privilege would be inappropriate here—however, at the very least CMS would be required to produce a privilege log of withheld documents as required by established Ninth Circuit authority. *Pac. Fisheries, Inc. v. United States*, 539 F.3d 1143, 1148 (9th Cir. 2008). We therefore are seeking a commitment from CMS to log any documents that are withheld under a claim of privilege.

Date Certain

As we mentioned, Mr. Balwani cannot identify the CMS witnesses he may need to depose without the documents, including the internal communications, and his ability to defend this case is substantially prejudiced with every passing day that the government continues to delay production.

Accordingly, please let us know no later than **February 20th** the government's position on the following:

- Will CMS commit to producing the responsive documents identified in this letter, including the internal communications from the custodians and dates ranges discussed above by a date certain?
- Will CMS commit to producing a privilege log for all responsive documents withheld on the grounds of the deliberative process privilege by a date certain?

Remaining Requests

Subject to the discussion above concerning the need for the government to commit to a date certain, your agreement to identify custodians from which documents will be collected, and commitment to a privilege log, we are agreeable to Ms. Turner's approach to the collection and production of documents responsive to the remaining requests of Mr. Balwani's subpoena. Of course, we reserve the right to seek additional materials should the need arise based on further developments in discovery

We look forward to hearing from you by February 20, 2019.

Best,

Davis Wright Tremaine LLP

Jeffrey B. Coopersmith

cc Lindsay Turner (via email – lindsay.turner@hhs.gov)
Marc D. Katz (via email – katzm@sec.gov)
Susan F. LaMarca (via email – lamarcas@sec.gov)

EXHIBIT B

Cazares, Steve

From: Coopersmith, Jeff
Sent: Wednesday, April 17, 2019 10:10 AM
To: Cazares, Steve; Gorton, Kelly
Subject: FW: SEC v. Balwani/FDA and CMS motions

I will be in LA and on my way to the aiport but could probably call in at around 11:30 am. Does that work for you as well?

From: Falk, Rebecca (USACAN) <Rebecca.Falk@usdoj.gov>
Sent: Wednesday, April 17, 2019 9:53 AM
To: Coopersmith, Jeff <JeffCoopersmith@dwt.com>
Cc: Cazares, Steve <SteveCazares@dwt.com>; Gorton, Kelly <KellyGorton@dwt.com>
Subject: RE: SEC v. Balwani/FDA and CMS motions

[EXTERNAL]

Jeff –

I'm available Wednesday, April 24 from 10-noon if there is a time in that window that works for you.

Best regards,
Rebecca A. Falk
Assistant United States Attorney
United States Attorney's Office
Northern District of California
450 Golden Gate Avenue, 9th Floor
San Francisco, California, 94102
T: 415-436-7022
F: 415-436-6748

From: Coopersmith, Jeff <JeffCoopersmith@dwt.com>
Sent: Tuesday, April 16, 2019 5:02 PM
To: Falk, Rebecca (USACAN) <rfalk@usa.doj.gov>
Cc: Cazares, Steve <SteveCazares@dwt.com>; Gorton, Kelly <KellyGorton@dwt.com>
Subject: RE: SEC v. Balwani/FDA and CMS motions

Rebecca, in reviewing the government's portions of these joint statements, I have a few questions to help frame the dispute for the court or perhaps narrow the disputes. Can we set up a call? Thanks.

Best,

Davis Wright Tremaine LLP

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Admitted in Washington, California, and the District of Columbia

From: Falk, Rebecca (USACAN) <Rebecca.Falk@usdoj.gov>
Sent: Thursday, April 11, 2019 1:09 PM
To: Coopersmith, Jeff <JeffCoopersmith@dwt.com>
Cc: Byer, Ben <BenByer@dwt.com>; Cazares, Steve <SteveCazares@dwt.com>; Gorton, Kelly <KellyGorton@dwt.com>; McDowell, Amanda <AmandaMcDowell@dwt.com>; lamarcas@sec.gov; katzma@sec.gov
Subject: RE: SEC v. Balwani/FDA and CMS motions

[EXTERNAL]

Jeff –

Attached please find both the FDA and CMS's contributions to the consolidated discovery letters for each agency.

You have my concurrence to file these letters in their current iteration. To the extent there are any changes to Mr. Balwani's statement, please send to me prior to filing so the agencies can respond.

I will not have any access to email until Monday. If you have any questions, I'll get back to you then.

Best regards,
Rebecca A. Falk
Assistant United States Attorney
United States Attorney's Office
Northern District of California
450 Golden Gate Avenue, 9th Floor
San Francisco, California, 94102
T: 415-436-7022
F: 415-436-6748

From: Coopersmith, Jeff <JeffCoopersmith@dwt.com>
Sent: Thursday, April 4, 2019 7:10 PM
To: Falk, Rebecca (USACAN) <rfalk@usa.doj.gov>
Cc: Byer, Ben <BenByer@dwt.com>; Cazares, Steve <SteveCazares@dwt.com>; Gorton, Kelly <KellyGorton@dwt.com>; McDowell, Amanda <AmandaMcDowell@dwt.com>; lamarcas@sec.gov; katzma@sec.gov
Subject: Re: SEC v. Balwani/FDA and CMS motions

Thanks Rebecca. Getting the government's responses by April 12 is fine.

Sent from my iPhone

On Apr 4, 2019, at 18:17, Falk, Rebecca (USACAN) <Rebecca.Falk@usdoj.gov> wrote:

> **[EXTERNAL]**

Dear Jeff –

The agencies are reviewing the drafts you sent. The government will provide responses by April 12. As one of your letters is dated March 22, it seems your team has had time to consider these issues, and the government requires the same.

Best regards,
Rebecca A. Falk
Assistant United States Attorney
United States Attorney's Office
Northern District of California
450 Golden Gate Avenue, 9th Floor
San Francisco, California, 94102
T: 415-436-7022
F: 415-436-6748

From: Coopersmith, Jeff <JeffCoopersmith@dwt.com>
Sent: Tuesday, April 02, 2019 6:45 PM
To: Falk, Rebecca (USACAN) <rfalk@usa.doj.gov>
Cc: Byer, Ben <BenByer@dwt.com>; Cazares, Steve <SteveCazares@dwt.com>; Gorton, Kelly <KellyGorton@dwt.com>; McDowell, Amanda <AmandaMcDowell@dwt.com>; lamarcas@sec.gov; katzma@sec.gov
Subject: SEC v. Balwani/FDA and CMS motions

Dear Rebecca,

I'm attaching two motions to compel, one addressing the issues regarding FDA and one addressing the issues regarding CMS. Each follows Judge Cousins's standing order providing that discovery disputes shall be addressed in a consolidated 5-page statement. We've included our positions and left space for the government's positions. We intend to file these motions no later than April 9, 2019, which allows plenty of time for the government to provide its portions. We look forward to receiving that from you. Thank you.

Best,

Davis Wright Tremaine LLP

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Anchorage | Bellevue | Los Angeles | New York | Portland | San Francisco | Seattle | Washington, D.C.

Admitted in Washington, California, and the District of Columbia

EXHIBIT C

Cazares, Steve

From: Falk, Rebecca (USACAN) <Rebecca.Falk@usdoj.gov>
Sent: Monday, June 3, 2019 2:59 PM
To: Cazares, Steve
Cc: Byer, Ben
Subject: RE: SEC v. Balwani - Supplemental Protective Order Re FDA-CMS

[EXTERNAL]

Steve –

Thanks for sending the protective order. Did the Theranos assignee grant the waiver? If so, please forward a copy so the agencies have it for reference.

In light of Monday's hearing on the requested stay of the SEC case, it seems to make sense to hold off having these conversations until we understand how the Court will rule. I'm happy to touch base after Monday's hearing to determine how to proceed.

Best regards,
Rebecca A. Falk
Assistant United States Attorney
United States Attorney's Office
Northern District of California
450 Golden Gate Avenue, 9th Floor
San Francisco, California, 94102
T: 415-436-7022
F: 415-436-6748

From: Cazares, Steve <SteveCazares@dwt.com>
Sent: Friday, May 31, 2019 9:59 AM
To: Falk, Rebecca (USACAN) <rfalk@usa.doj.gov>
Cc: Byer, Ben <BenByer@dwt.com>
Subject: SEC v. Balwani - Supplemental Protective Order Re FDA-CMS

Rebecca,

Attached is the Supplemental Protective Order relating to the FDA and CMS signed by MJ Cousins yesterday. Can we schedule a call to discuss what the agencies have done to advance these productions, ie what searches have been done, what custodians have been utilized, and when we can expect the productions to begin? If not today (I am available most of the day), can we do a call on Monday?

Thank you

Steve

Stephen A. Cazares | Partner
Davis Wright Tremaine LLP
865 S Figueroa Street, Suite 2400 | Los Angeles, CA 90017
Tel: (213) 633-8607 | Fax: (213) 633-6899
Email: stevecazares@dwt.com | Website: www.dwt.com

EXHIBIT D

Cazares, Steve

From: Falk, Rebecca (USACAN) <Rebecca.Falk@usdoj.gov>
Sent: Monday, June 17, 2019 11:38 AM
To: Cazares, Steve
Cc: Coopersmith, Jeff
Subject: RE: SEC v. Balwani - Subpoenas to FDA-CMS

[EXTERNAL]

Steve –

Thanks for passing this along. This case has been reassigned in our office, so I will be back in touch with contact information and then you can work out a schedule for a call with the assigned AUSA.

Best regards,
Rebecca A. Falk
Assistant United States Attorney
United States Attorney's Office
Northern District of California
450 Golden Gate Avenue, 9th Floor
San Francisco, California, 94102
T: 415-436-7022
F: 415-436-6748

From: Cazares, Steve <SteveCazares@dwt.com>
Sent: Friday, June 14, 2019 4:43 PM
To: Falk, Rebecca (USACAN) <rfalk@usa.doj.gov>
Cc: Coopersmith, Jeff <JeffCoopersmith@dwt.com>
Subject: SEC v. Balwani - Subpoenas to FDA-CMS

Rebecca,

You may or may not have heard, but this afternoon Judge Davila denied the motion to stay discovery, copy attached. In light of this development, we have some questions regarding the expected productions by the FDA and CMS. Can we get together on a phone call Monday afternoon to discuss?

Thanks,

Steve

Stephen A. Cazares | Partner
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865 S Figueroa Street, Suite 2400 | Los Angeles, CA 90017
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EXHIBIT E

Cazares, Steve

From: Cormier, Claire (USACAN) <Claire.Cormier@usdoj.gov>
Sent: Friday, June 21, 2019 4:08 PM
To: Cazares, Steve
Cc: Coopersmith, Jeff
Subject: FW: SEC v. Balwani - Subpoenas to FDA-CMS

[EXTERNAL]

Steve,
I wanted to introduce myself since I will be taking over the Balwani subpoena matter from Rebecca Falk, who is leaving our office.

As you noted, it will take me some time to get up to speed, but FDA and CMS have been working on moving forward with the productions while waiting for the recent waiver and new protective order, as well as the recent decision on the motion to stay, and they will continue while I learn more about this case.

I have consulted with FDA and CMS and can give you some updates on the productions they are working on to supplement the approximately 55,000 pages from FDA and 250,000 pages from CMS previously provided to you. Barring technical or other difficulties, both CMS and FDA currently anticipate that they will begin additional productions in response to your client's Rule 45 subpoenas to the agencies in approximately a month. It is possible that goal could be stretched a bit depending on the availability of some necessary resources, but that is the current estimate.

I look forward to resolving the remaining issues relating to the subpoenas as expeditiously as possible.

My contact information is below.

Claire T. Cormier
Assistant U.S. Attorney
150 Almaden Blvd., Suite 900
San Jose, CA 95113
408-535-5082 (Direct)
408-535-5061 (Main)
408-535-5081 (Fax)
claire.cormier@usdoj.gov

From: Falk, Rebecca (USACAN) <rfalk@usa.doj.gov>
Sent: Thursday, June 20, 2019 1:20 PM
To: Cormier, Claire (USACAN) <CCormier@usa.doj.gov>
Subject: FW: SEC v. Balwani - Subpoenas to FDA-CMS

Rebecca A. Falk
Assistant United States Attorney
United States Attorney's Office
Northern District of California

450 Golden Gate Avenue, 9th Floor
San Francisco, California, 94102
T: 415-436-7022
F: 415-436-6748

From: Cazares, Steve <SteveCazares@dwt.com>
Sent: Monday, June 17, 2019 12:03 PM
To: Falk, Rebecca (USACAN) <rfalk@usa.doj.gov>
Cc: Coopersmith, Jeff <JeffCoopersmith@dwt.com>
Subject: RE: SEC v. Balwani - Subpoenas to FDA-CMS

Rebecca,

We appreciate the fact that you may not control case staffing within the USAO, but these delays are prejudicing our client. On May 31, 2019, we provided you and FDA-CMS a copy of the supplemental protective order to facilitate production by the agencies. At that time, we requested a telephone call to discuss the production efforts by agencies to date, and logistics going forward. On June 3, 2019, in response, you deferred any discussions of the agency productions until after the June 10, 2019 hearing on the SEC's motion to stay discovery. This deferral was notwithstanding the fact that we, on behalf of Mr. Balwani, have been trying to obtain a complete production from the agencies since the subpoenas were originally issued in September 2018. On June 11, 2019, we further provided to you and the agencies with a copy of the waiver of trade secret and other confidentiality issues by the assignee for Theranos to further facilitate the agencies' productions.

Now, apparently, a new AUSA in the civil division will be assigned and need time to review the file and get up to speed before we can then proceed to make progress in obtaining documents in response to subpoenas issued 9 months ago. This is not acceptable. Please advise the new AUSA or whoever the supervisor is in the civil division that we expect a telephone call to discuss the agencies' productions this week.

Thank you,

Steve

Stephen A. Cazares | Partner
Davis Wright Tremaine LLP
865 S Figueroa Street, Suite 2400 | Los Angeles, CA 90017
Tel: (213) 633-8607 | Fax: (213) 633-6899
Email: stevecazares@dwt.com | Website: www.dwt.com

Anchorage | Bellevue | Los Angeles | New York | Portland | San Francisco | Seattle | Washington, D.C.

From: Falk, Rebecca (USACAN) <Rebecca.Falk@usdoj.gov>
Sent: Monday, June 17, 2019 11:38 AM
To: Cazares, Steve <SteveCazares@dwt.com>
Cc: Coopersmith, Jeff <JeffCoopersmith@dwt.com>
Subject: RE: SEC v. Balwani - Subpoenas to FDA-CMS

[EXTERNAL]

Steve –

Thanks for passing this along. This case has been reassigned in our office, so I will be back in touch with contact information and then you can work out a schedule for a call with the assigned AUSA.

Best regards,
Rebecca A. Falk

Assistant United States Attorney
United States Attorney's Office
Northern District of California
450 Golden Gate Avenue, 9th Floor
San Francisco, California, 94102
T: 415-436-7022
F: 415-436-6748

From: Cazares, Steve <SteveCazares@dwt.com>
Sent: Friday, June 14, 2019 4:43 PM
To: Falk, Rebecca (USACAN) <rfalk@usa.doj.gov>
Cc: Coopersmith, Jeff <JeffCoopersmith@dwt.com>
Subject: SEC v. Balwani - Subpoenas to FDA-CMS

Rebecca,

You may or may not have heard, but this afternoon Judge Davila denied the motion to stay discovery, copy attached. In light of this development, we have some questions regarding the expected productions by the FDA and CMS. Can we get together on a phone call Monday afternoon to discuss?

Thanks,

Steve

Stephen A. Cazares | Partner
Davis Wright Tremaine LLP
865 S Figueroa Street, Suite 2400 | Los Angeles, CA 90017
Tel: (213) 633-8607 | Fax: (213) 633-6899
Email: stevecazares@dwt.com | Website: www.dwt.com

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EXHIBIT F

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

March 22, 2019

VIA Electronic Mail and UPS

Jeffrey Coopersmith, Esq.
Davis Wright Tremaine LLP
505 Montgomery St., Suite 800
San Francisco, CA 94111

Re: Subpoena issued to United States Food and Drug Administration in *Securities and Exchange Commission v. Ramesh "Sunny" Balwani;* Civil Action No. 5:18-CV-01603-EJD (N.D. Cal.)

Dear Mr. Coopersmith:

This letter responds to the third-party subpoena to the United States Food and Drug Administration (FDA) in the above-referenced case, issued by you on March 15, 2019, to Rebecca Falk in the Department of Justice (DOJ). FDA had not waived service or authorized Ms. Falk to accept service on its behalf prior to your firm's purported "re-issuance" of its earlier subpoena by way of an email to Ms. Falk, and FDA has no record of any other service of this document. In an effort to move this matter forward, however, FDA has authorized Ms. Falk to accept service specifically of this subpoena on its behalf. This letter sets forth our objections to your subpoena pursuant to Rule 45(d)(2)(B) of the Federal Rules of Civil Procedure.[1]

Your subpoena requests 20 broad categories of documents, correspondence, and communications (hereafter, "documents") referring to or relating in any way to Theranos, Inc. (Theranos), Elizabeth Holmes, and Ramesh "Sunny" Balwani, from the eight and a half year period from January 2010 through June 2018, including, among other things, internal FDA documents and documents between FDA and the following entities: DOJ, the Department of Defense (DOD), the Centers for Medicare & Medicaid Services (CMS), members of Congress, the media, the health care industry, laboratories and laboratory associations.

When FDA initially received your subpoena on September 14, 2018, it was unaware that you were already in possession of more than 40,000 pages provided by FDA to the SEC in connection with its civil case against Mr. Balwani and/or to DOJ in connection with its criminal case against Mr. Balwani. Because FDA did not know this, the agency began processing your subpoena by preparing and producing the documents that FDA gave to the SEC and DOJ, and it provided you over 4,200 pages of documents in four separate

[1] Because FDA has not completed its review of all responsive documents, this written objection may not include all possible bases for objection. FDA reserves the right to assert later that additional bases exist for objecting to the disclosure of the requested documents.

productions between October 16 and 24, 2018. However, once FDA became aware that you already had the documents the agency had previously produced to the SEC and DOJ, we informed your colleagues Ben Byer and Amanda McDowell that we were going search for new responsive documents and emails responsive to the subpoena. During multiple calls, we explained the steps we were taking and why it would speed up the process if we received a waiver from Theranos, which would allow FDA to produce lesser-redacted documents more quickly. FDA made several unsuccessful attempts to obtain a waiver in this case, but Mr. Byer stated that he would obtain a waiver that would permit FDA to produce documents containing Theranos' trade secret and confidential commercial information (CCI). We have not yet received a waiver.

Although FDA has not yet had collected and reviewed all documents that may be responsive to your subpoena, based on our initial assessment, it appears that the Federal Rules of Civil Procedure, federal law, and discovery privileges may prevent FDA from disclosing some portion of the requested documents to you.

Below, I explain the grounds for these objections based on our preliminary evaluation.

Prohibition on FDA's Disclosure of Trade Secret and Confidential Commercial Information

FDA is specifically prohibited from releasing trade secret information obtained under certain of its regulatory authorities in a judicial proceeding that is not brought under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(j), and FDA is also prohibited from releasing trade secrets and CCI regarding devices obtained through the agency's regulatory and inspectional authorities, 21 U.S.C. § 360j(c). In addition, the Trade Secrets Act, 18 U.S.C. § 1905, prohibits FDA from releasing trade secrets and CCI unless otherwise authorized by law. Further, FDA regulations provide that trade secrets and CCI are not available for public disclosure. *See* 21 C.F.R. § 20.61. Accordingly, FDA is unable to produce any responsive information that would reveal trade secrets and/or confidential research, development, or commercial information. *See also* Fed. R. Civ. P. 45(d)(3)(B)(i).

The extent to which the agency will be required to redact responsive documents prior to producing them to you, as well as the speed at which FDA will be able to produce these documents, largely depends upon whether Theranos or its assignee authorizes FDA to release trade secrets or CCI to Mr. Balwani and whether the parties in the above-referenced case have entered into an acceptable protective order that would protect the trade secrets and CCI that FDA would otherwise need to identify and withhold. Should Theranos or its assignee provide FDA with an acceptable waiver, FDA would not be required to redact the company's trade secrets and CCI from the responsive documents; the agency would, however, still must review and redact any third party's trade secrets or CCI from responsive documents.

Objections Based on Other Privileges

FDA has agreed to waive its deliberative process privilege with respect to Theranos documents. However, your subpoena seeks disclosure of materials that are or contain attorney-client communications, attorney work product, personal privacy information, privileged investigatory files, and/or other protected information, and FDA objects to disclosure on those bases as well. *See* Fed. R. Civ. P. 45(c)(3)(A)(iii); *see also* 21 C.F.R. §§ 20.62, 20.63, 20.64. Before any documents can be provided to you, FDA will have to review and redact any such privileged information.

Responsive Documents Are Available from Another Source

FDA also objects to your subpoena to the extent that it requests documents which, even if contained in FDA files, are available elsewhere. Specifically, you request documents that may belong to, or relate to activities of Mr. Balwani, a party in the underlying litigation and Theranos, the company for which Mr. Balwani served as President and Chief Operating Officer, as well as non-government third parties. Accordingly, we object to your request for these documents under Rule 45, Rule 26(b)(2)(C), and 21 C.F.R § 20.51, as the documents could be obtained more easily from Mr. Balwani or non-government third parties, thus sparing the use of taxpayer resources.

The Subpoena is Overly Broad and Unduly Burdensome

The subpoena is also overly broad and unduly burdensome. *See* Fed. R. Civ. P. 45(d)(1), (d)(3)(A)(iv); 21 C.F.R § 20.50. As noted, your subpoena is quite expansive and potentially covers a large number of documents over a long-time period. As discussed above, your requests encompass documents that may contain trade secrets and CCI protected from release or disclosure under applicable statutes, regulations, and privileges. Thus, responding to your subpoena as currently drafted requires a significant amount of time to collect and review a large number of potentially responsive documents for possible production.

Moreover, FDA is currently faced with many other voluminous document requests, including Freedom of Information Act requests, Congressional requests, and other subpoenas, and the agency employs a queue approach to processing these document requests. Given the existing document production demands on FDA and the time needed to review the large number of documents responsive to your subpoena, it will take a significant amount of FDA employee time to prepare these documents for production in litigation in which FDA is not a party. This effort would deprive FDA of valuable resources and put a strain on the agency's resources. Your subpoena imposes a burden on FDA that is not proportional to the agency's role and relevance in the SEC case. Accordingly, we object to the subpoena pursuant to Rule 45 and 21 C.F.R § 20.50 as overly broad and unduly burdensome.

Objection Based on Geographical Limits

Pursuant to Rule 45(d)(3)(A)(ii), a district court must quash or modify a subpoena if it "requires a person to comply beyond the geographical limits specified in Rule 45(c)." Under Rule 45(c)(2), "[a] subpoena may command: (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person . . . ." The present subpoena, requires FDA, a non-party, to produce documents in San Francisco, CA. The records responsive to your subpoena are located in Silver Spring, MD. Because the subpoena does not meet the requirements of Rule 45(c)(2), the subpoena is invalid and unenforceable. See Fed. R. Civ. P. 45(c)(2) & (d)(3)(A)(ii).

Conclusion

Notwithstanding the foregoing, FDA is committed to working with you to resolve this matter and to produce documents in a manner that is consistent with federal law, agency procedures, and FDA's commitments and obligations in other matters, and which does not subject the agency to an unreasonable burden. The agency has already expended a significant amount of resources to respond to document requests in connection with the SEC's civil case and DOJ's criminal case against your client and will continue to do so as it reviews and prepares additional responsive, non-privileged documents for production in response to your subpoena. We are doing our best to get you the documents you want as quickly as possible, considering the large volume of documents and the agency's other pressing responsibilities. Once you have obtained a waiver from the Theranos assignee and the Supplemental Stipulated Protective Order governing FDA and CMS documents is entered by the Court, FDA will produce additional records to you in response to the subpoena.

If you have any further questions, please contact AUSA Rebecca Falk at 415-436-7022.

Sincerely,

Laura J. Draski -S

Digitally signed by Laura J. Draski -S
Date: 2019.03.22 15:20:14 -04'00'

CAPT Laura Draski, PhD
Acting Director
Office of Strategic Planning and Operational Policy
Office of Regulatory Affairs
U.S. Food and Drug Administration

EXHIBIT G

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the General Counsel
Centers for Medicare &
Medicaid Services Division

330 Independence Ave., S.W.
Room 5309 Wilbur J. Cohen Building
Washington, D.C. 20201

September 27, 2018

Jeffrey Coopersmith
Davis Wright Tremaine LLP
505 Montgomery Street, Suite 800
San Francisco, CA 94111

Dear Mr. Coopersmith,

This letter responds to the Rule 45 discovery subpoena that you served on behalf of Ramesh Balwani, the defendant in *SEC v. Ramesh "Sunny" Balwani*, No. 18-cv-01603 (N.D. Cal.) on the U.S. Department of Health & Human Services ("HHS"), Office of the General Counsel ("OGC"), which was received by the OGC on or about September 14, 2018.

We write to provide you with a brief statement of our objections to your September 14, 2018 subpoena. Because our review of the subpoena continues, we reserve the right to supplement these objections in the future. We also specifically reserve and do not waive other objections that may be applicable in discovery or at trial.

First, we object to the subpoena as vague and ambiguous, overly broad and unduly burdensome. For example, the definition of "YOU," "YOUR," and "YOURS" is vague and ambiguous, overly broad and unduly burdensome to the extent it includes parties beyond CMS and CMS contractors. The definitions of "LAB OR LAB ASSOCIATION" and "HEALTH CARE INDUSTRY" and the document request that use those terms (Nos. 13 and 15) are also vague and ambiguous, overly broad and unduly burdensome. The definition of "LAB OR LAB ASSOCIATION" includes all clinical laboratories in existence, all industry or trade associations, and any persons or entities in any way affiliated or associated with such clinical laboratories or industry or trade associations. The definition of "HEALTH CARE INDUSTRY" is defined to refer to the entire health care industry and any person or entity associated with anyone in the health care industry.

Second, we object to Instruction No. 21 to the extent that it assumes that some degree of document search is always possible, notwithstanding an objection based on vagueness, ambiguity, overbreath and/or undue burden.

Third, we object to Instruction No. 23 that purports to require the production of a privilege log for those document requests where we have objected in full and for document requests that seek privileged information.

Fourth, we object to the subpoena to the extent it requests documents that we believe are already in the possession of the Defendant, or could easily be obtained through other means. For example, the subpoena seeks communications about meetings and calls CMS had with Theranos, Ms. Holmes, or Mr. Balwani. The Defendant should already have access to communications, meetings, and calls that his company had with CMS. The subpoena also seeks documents and communications relating to Theranos's compliance with CLIA regulations and any CMS Form 2567 and/or Plan of Correction relating to Theranos. Any responsive documents should already be in the possession of the Defendant, except for internal deliberative CMS communications that are protected by the deliberative process privilege.

Fifth, we object to the extent the subpoena asks for documents and communications relating to Theranos's compliance with state law because those documents are not within the custody and control of CMS.

Sixth, we object to the subpoena to the extent it requires HHS to draw legal conclusions or otherwise seeks to impose upon HHS any requirements beyond those established by the Federal Rules of Civil Procedure or the Local Rules of the United States District Court for the Northern District of California.

Seventh, we object to the subpoena to the extent that it seeks information or documents protected from disclosure by privilege or doctrine, including the attorney-client privilege, the investigative file privilege, the work product privilege, the deliberative process privilege, the law enforcement privilege, or any other applicable basis for invoking privilege. *See* Fed. R. Civ. P. 45(c)(3)(A)(iii). For example, the subpoena seeks internal CMS communications about the 2567 and the Plan of Correction that are predecisional and deliberative.

Eighth, we object to the subpoena to the extent it seeks confidential information on individual Medicare beneficiaries that is protected from disclosure by Federal law, specifically section 1106 of the Social Security Act, 42 U.S.C. § 1306, and the Privacy Act of 1974, 5 U.S.C. § 552a. *See also* 42 C.F.R. § 401.105; 45 C.F.R. § 5b.9 and § 164.512(e).

Finally, we object to the subpoena on the ground that the time provided to produce documents is unreasonable. *See* Fed. R. Civ. P. 45(c)(3)(A)(i). The subpoena requests 8 years of data on a variety of overly broad topics. Given the time needed to identify, collect, and process the data responsive to this extremely broad subpoena, directing CMS to respond by October 15, 2018 is unreasonable.

We are committed to working with you to resolve these concerns and produce responsive data in a manner consistent with federal law, regulations, and procedure, without subjecting the Department to an unreasonable burden. Please contact me directly at Lindsay.Turner@hhs.gov to set up a call to discuss this matter further.

Sincerely,

Lindsay Turner
Office of the General Counsel-CMS Division
U.S. Department of Health & Human Services
(202) 205-5867
Lindsay.Turner@hhs.gov

cc: Sara Winslow, Chief, Civil Division, U.S. Attorney's Office, Northern District of California